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| 09/771,933      | 01/30/2001  | Rosalynn D. Gill-Garrison | 620-130             | 9089             |

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/771,933

Applicant(s)

GILL-GARRISON ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/25/04; 7/29/04; 8/19/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 25 June 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-28 are currently pending.

#### **Information Disclosure Statement**

The Information Disclosure Statements filed 25 June 2004, 29 July 2004, and 19 August 2004 have been considered. Signed copies of PTO Forms 1449 are included with this Office Action.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-28 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are as follows:

Claims 1 and 14 further recite (iii) inputting a third dataset identifying alleles at one (two) or more of the genetic loci of said first dataset of said human subject. It appears that this step is missing an element which makes it clear whether the input data from the individual human sample in step (iii) is different from the dataset of (i), which includes all of the known disease associated alleles.

Claims 1 and 14 recite (iv) determining the risk factors associated with said alleles of said human subject using the first dataset. Again, it seems that an element is missing in (i) such that it is unclear whether the risk factors identified in (iv) are performed by comparing the individual's data with a set of generic, known data generated from a variety of samples.

Claims 1 and 14 recite (v) determining at least one lifestyle recommendation based on each identified risk factor from step (iv) using said second dataset. Again, how does the data of this step relate to said dataset for step (ii)?

Claims 1 and 14 recite (vi) generating a personalized lifestyle advice plan based on said lifestyle recommendations. Does this mean that the lifestyle recommendation of the individual is generated based upon associated known risk factors of the second dataset? If so, it is still unclear that the second dataset is a dataset which is different from that of the patient (individual) sample.

Finally, it is unclear at step (iii) from where the third dataset is derived. It would seem that an essential element would be to actually determine the alleles from the individual sample such that they could be input and then evaluated. Clarification is requested.

Art Unit: 1631

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,985,559 (Brown; PTO Form 1449), in view of Perera et al. (Carcinogenesis (2000) Volume 21, pages 517-524; PTO Form 1449), for the reasons set forth in the previous Office Action.

*New Claims*

New claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,985,559 (Brown; PTO Form 1449), in view of Perera et al. (Carcinogenesis (2000) Volume 21, pages 517-524; PTO Form 1449).

The present invention is drawn to a computer assisted method of providing a personalized lifestyle advice plan comprising providing datasets, identifying alleles, determining risk factors, determining lifestyle recommendations, and generating a lifestyle plan.

Brown teaches a computer system and method for interpreting a patient's gene sequence and his or her environment and lifestyle to come up with a personalized prognosis. The system consists of a health monitor which can read a patient's gene sequence (a dataset of genetic information) and scripts which correspond to information relevant to a disease associated with the gene sequence. A secondary script can be generated, allowing for a dynamic between genes and disease. The end result is a determination of the condition or phenotype associated with the patient's genotype or gene sequence. These events can be repeated over a series of time (column 2, lines 38-63) (claims 1, 3, 4).

Brown does not specifically teach particular alleles associated with disease and that two or more may be used to determine risk, however Perera et al. do propose a framework for implementing various biomarkers for assessment of individual risk factors (see abstract).

Specifically, Perera et al. show that common genetic traits, such as those that regulate metabolism and detoxification of carcinogens can have a major impact on the population attributable risk of cancer. For example, cytochrome P450 phase I enzymes can produce highly reactive DNA-damaging intermediates during the normal process of converting chemical

Art Unit: 1631

carcinogens to excretable forms (claims 6, 7, 10, 11, 12). Polymorphic variations in P450s have been shown to be associated with increase cancer risk in various populations. Furthermore, interindividual variation in phase II detoxifying enzymes, such as glutathione-S-transferase, can also contribute to individual susceptibility (page 520, column 1, lines 19-34) (claims 8, 9, 12, and 13). Perera et al. further disclose that study designs have become increasingly complex and multiple markers are frequently assessed (page 520, column 2, lines 44-56).

Perera et al. also disclose that individuals who have a methyl-deficient diet are at higher risk of colon cancer if they carry a defective polymorphic form of the enzyme methylene tetrahydrofolate reductase (page 521, lines 28-32) (claim 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the system of Brown with the polymorphic marker information of Perera et al. to provide lifestyle advice plan based upon risk factors. One would have been motivated to combine the various markers in the assessment of a patient's predisposition to disease as suggested by Perera et al. at page 521, lines 50-63:

"A recent trend that brings together cancer researchers interested in cancer epidemiology, chemoprevention, and therapy is the increasing recognition that biomarkers developed in the field of molecular epidemiology may also be useful as early or intermediate endpoints in studies on cancer prevention by identifying 'at risk' populations and then assessing the efficacy of various types of intervention. For example, in interventions to prevent first or second malignancies, biomarkers can help identify populations or individuals at high risk of cancer resulting from specific environment-gene interactions".

***Response to Applicants Arguments***

Applicant argues that it is not clear from Brown how one is to provide a dataset containing information matching a lifestyle risk factor with at least one lifestyle recommendation. However, this is not persuasive because Brown does teach a lifestyle risk factor, i.e. the risk of having cystic fibrosis. The risk factor is necessarily associated with a lifestyle recommendation in a database in order for the computer to provide a treatment plan (column 5, lines 45-54). "Using the information generated by the health monitor, a personalized treatment can be created for the patient"(line 51).

Applicant further argues that Brown provides examples of cystic fibrosis and Gaucher disease, as alleles of genetic loci of the human subject and that these diseases are inherited genetic disorders for which personalized treatment is not likely to be available. This is not persuasive because the claims do not recite that inherited genetic disorders are excluded. Brown specifically teaches a personalized treatment plan, as set forth above. The claims do not require any specific plans or design of any specific plan. It is unclear what Applicant means by teaching a "realistic embodiment". For example, treatment for cystic fibrosis is well-known in the art and would constitute a realistic embodiment for practicing said invention.

Applicant argues that Perera teaches, at best, an invitation to develop means to produce a lifestyle plan. This is not persuasive because Perera is not relied upon to teach a lifestyle plan. This limitation is taught by Brown, as indicated above. Perera is relied upon to teach allele recognition associated with lifestyle risks. For the reasons previously set forth and above, the Examiner maintains that the combination of Brown and Perera makes obvious the claimed method.



Art Unit: 1631

### Conclusions

Applicant requested that the Examiner clarify whether or not the search over the prior art had been expanded to include the non-elected species of A and B. In the previous Office Action, the Examiner searched the claims commensurate in scope with the elected species A and B.

The rejections under 35 USC 112, 1<sup>st</sup> paragraph have been withdrawn in view of Applicant's response.

The rejections under 35 USC 112, 2<sup>nd</sup> paragraph pertaining to the last Office Action have been withdrawn in view of Applicant's response.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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December 17, 2004  
Lori A. Clow, Ph.D.  
Art Unit 1631

*Lori A. Clow*

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*  
12/22/04